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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/821,284

04/09/2004

Bradley Moore

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04/23/2009

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NEW BRUNSWICK, NJ 08933-7003

EXAMINER

HOFFMAN, MARY C

ART UNIT

PAPER NUMBER

3733

MAIL DATE

DELIVERY MODE

04/23/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/821,284	Applicant(s) MOORE ET AL.	
	Examiner MARY HOFFMAN	Art Unit 3733	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 February 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 37-47 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 37-47 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 16 October 2007 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Objections

Claims 38, 42 and 43 are objected to because of the following informalities:

Claims 38, 42 and 43 use the term "fixation element" rather than "rod." The claims should be amended to recite consistent terminology. Appropriate correction is required.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

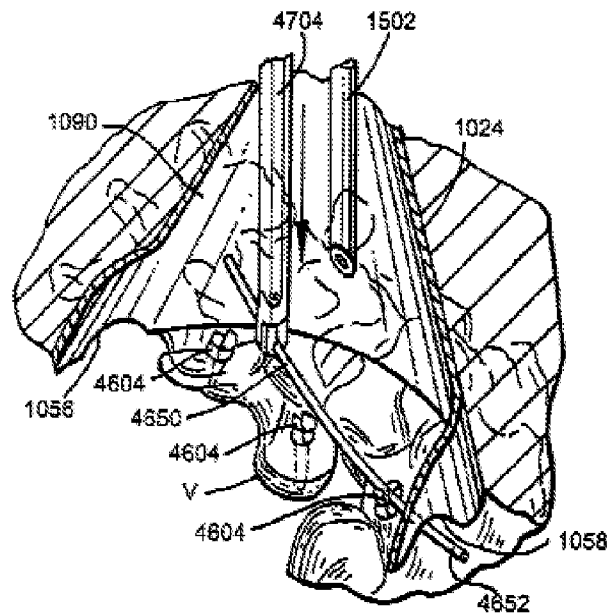
Claims 37-47 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pagliuca et al. (US 2003/0073998) in view of Chin (US 2005/0065517, see Provisional Application 60518580) and Shluzas (US 20040230100).

Pagliuca et al. disclose a minimally invasive surgical method comprising making a first incision in a patient; inserting a retractor (1024) and expanding it, advancing a first anchor (4604) through (a first pathway) via the expanded retractor to a first anchor site on a first vertebra; and advancing a second anchor (4604) through the expanded retractor to a second anchor site on a second vertebra adjacent the first vertebra.

Pagliuca further discloses positioning a first end of a spinal rod (4650) in the expanded

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retractor; advancing the first end of the spinal rod subcutaneously; and coupling the spinal rod to the first anchor and the second anchor.



Disk material is removed from the disk space between the first and second vertebrae through the first pathway, the method further comprising inserting bone graft into the disk space, the method further comprising inserting an interbody fusion device into the disk space (FIG. 70, claim 14). The retractor has an opening (1056, 1058) that allows the rod to pass through it.

Pagliuca et al. disclose the claimed invention except for the steps of 1.) making a percutaneous incision in the patient and creating a second pathway to the third vertebra by dilating the incision and inserting a cannula/percutaneous access device, advancing a third anchor through the percutaneous incision to a third anchor site on the third vertebra; advancing the first end of the rod subcutaneously/subfascially to the third

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anchor; and advancing a closure mechanism through the lumen of the percutaneous access device; and further comprising a second rod, and a fourth, fifth, and a sixth anchor, and 2.) the retractor having a plurality of expandable retractor blades and expanding the retractor by separating the retractor blades.

Chin discloses making a percutaneous incision in the patient; creating a second pathway to the third vertebra by dilating the incision and inserting a cannula/percutaneous access device, advancing a third anchor through the percutaneous incision to a third anchor site on the third vertebra; advancing the first end of the rod subcutaneously/subfascially to the third anchor; to perform minimally invasive surgery. (It is noted that the Chin method represents an improvement over the Pagliuca et al. method. The incisions required by Chin are much smaller, and are therefore less invasive, and would be especially useful in surgeries spanning larger areas (for example, in surgeries where more than three bone anchors are used on each side of the spine).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to perform the method of Pagliuca et al. making a percutaneous incision in the patient; creating a second pathway to the third vertebra by dilating the incision and inserting a cannula/percutaneous access device (see FIGS. 2a-b) having an opening to facilitate coupling to the rod element, advancing a third anchor through the percutaneous incision to a third anchor site on the third vertebra; advancing the first end of the rod element subcutaneously/subfascially to the third anchor (See FIG. 9); and advancing a closure mechanism through the lumen of the percutaneous access

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device in view of Chin to perform minimally invasive surgery. Chin would allow installation of many bone anchors (more than just the three anchors as disclosed in Pagliuca et al.) without requiring a long incision or multiple larger incisions for expandable retractor blades, while still maintaining a larger working space inside the body in which the surgeon could more easily initially insert the spinal rod before passing it through the body percutaneously and also use an endoscope. Moreover, the method of Pagliuca et al. for insertion of the rod through the expandable retractor might be desirable to surgeons already trained on and familiar with the tools of Pagliuca et al. used to insert the rod through the larger expandable retractor blades; surgeons might be slow to use the less familiar tools needed in Chin to insert the spinal rod through the narrow insertion cannula, even while recognizing the benefit provided by passing the spinal rod under the skin as taught by Chin.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to perform the method of Pagliuca in view of Chin using a second rod, and a fourth, fifth, and a sixth anchor (a second system on the opposite side of the spine), since it has been held that mere duplication involves only routine skill in the art. *St. Regis Paper Co. v. Bemis Co.*, 193 USPQ 8.

2.) Shluzas disclose using a retractor having a plurality of expandable retractor blades and expanding the retractor by separating the retractor blades (paragraph [0145], see FIG. 12).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to perform the method of Pagliuca with a retractor having a plurality

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of expandable retractor blades and expanding the retractor by separating the retractor blades in view of Shluzas, since such is a functional equivalent of the single blade expandable retractor disclosed in Pagliuca et al. and would provide the same predictable result of allowing access into a working space within the body.

Response to Arguments

Applicant's arguments filed 02/04/2009 have been fully considered but they are not persuasive.

The examiner has provided a more detailed rationale as to why it would have been obvious to one of ordinary skill in the art to combine Pagliuca et al. with Chin. In particular, the examiner maintains that combining the two seemingly compatible methods into one hybrid method would have been obvious to one of ordinary skill in the art. As discussed above, the Chin method is less invasive, and would be useful in surgeries spanning larger areas of the spine. Thus, combining the two methods into one hybrid method allows for a larger working space through the expandable retractor for the surgeon to insert a spinal rod and use an endoscope, while at the same time being less invasive in surgeries requiring more than three anchors.

Regarding Applicant's argument that Chin teaches away from Pagliuca et al., the examiner respectfully disagrees. Chin is an improvement over Pagliuca et al., but there does not appear to be any evidence in either reference that would cause a person of ordinary skill in the art to believe that the Pagliuca et al. and Chin could not be

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combined. Teaching a better way, *i.e.* an improvement, is not considered teaching away.

The rejections are deemed proper.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MARY HOFFMAN whose telephone number is (571)272-5566. The examiner can normally be reached on Monday-Thursday 10:00-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo C. Robert can be reached on 571-272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Mary C. Hoffman/
Examiner, Art Unit 3733
/Eduardo C. Robert/
Supervisory Patent Examiner, Art Unit 3733